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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,728	06/14/2006	Alberto Osio Sancho	2005735-0004	4669
24280 7590 07/07/2010 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110			EXAMINER SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			07/07/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/582,728	<b>Applicant(s)</b> OSIO SANCHO, ALBERTO	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 15, 17 and 25-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-14, 16 and 18-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/25/07; 10/31/08</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Response to Restriction/Election and Applicant's Arguments/Remarks, all filed 04/05/10 and the Information Disclosure Statements (IDS) filed 05/25/07 and 10/31/08 is acknowledged.

Applicant's election without traverse of Group I (claims 1-27) and Election of Species: of 1(a) inducing a change in corneal power; 2(a) methylcellulose, cellulose; 3(b) gel, semi-solid gel; 4(b) hypotonic; 5(a) hyaluronidase and 6(a) presbyopia in the reply filed on 05 April 2010 is acknowledged.

Claims 4-7, 15, 17 and 25-50 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05 April 2010.

Claims 1-50 are pending in this action. Claims 4-7, 15, 17 and 25-50 have been withdrawn (based on nonelected invention). Claims 1-3, 8-14, 16 and 18-24 have been examined in this action. Claims 1-3, 8-14, 16 and 18-24 are rejected.

\* \* \* \* \*

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 05/25/07 and 10/31/08 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

\* \* \* \* \*

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***Claim Objections***

Claim 21 is objected to because of the following informalities: Claim 21 recites the phrase “at least 1 years”. The term “years” which occurs in plural form should be changed to “year” (singular form) to be grammatically correct. Appropriate correction is required.

\* \* \* \* \*

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, 8, 9, 11-13, 18, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris *et al.* (hereinafter “Harris” (EP 0 608 341).**

**Harris** (‘341) discloses methods for accelerated corneal reshaping involving the release of enzymes, particularly hyaluronidase, or other agent which facilitate reshaping of the cornea to reduce or eliminate refractive errors of the eye (page 2, lines 3-5). (This reads on Applicant’s method for treating ophthalmologic conditions). The methods employ a contact lens for delivering agents to the eye and utilize hyaluronidase for the manufacture of a medicament for the treatment of refractive errors of the eye. An agent that softens the cornea of a mammalian eye for use in correcting refractive errors is also disclosed. The agent can be provided in combination with a rigid contact lens. The medicament may further comprise an anesthetic (p. 3, lines 13-38). The medicaments permit a method of reshaping a cornea from a first configuration to a second desired configuration in order to correct refractive errors in an eye (p. 3, line 39 – p.

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4, line 5). The lens is removed when the cornea is capable of maintaining the desired second configuration without the support of the lens (p. 5, lines 8-9). The corneal agent(s) such as enzymes and enzyme activators can be administered in the form of eye drops (p. 4, lines 6-21). Where the corneal softening agent used is hyaluronidase, the inhibitor can be a hyaluronidase inhibitor such as cysteine and EDTA. Collagenase is also disclosed (p. 4, lines 34-42). The primary enzyme used to soften a cornea is hyaluronidase (p. 6, line 32).

These teachings read on and meet the limitations of instant claims 1-3, 8, 9, 11-13, 18, 22 and 23. Hence, the instant claims are anticipated by Harris.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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**Claims 10, 14, 16, 19-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris *et al.* (hereinafter “Harris” (EP 0 608 341) in view of Marmo *et al.* (hereinafter “Marmo”) (U.S. Pat. Appln. Publn. No. 2005/0080484).**

The teachings of Harris are discussed above.

Harris does not teach the vehicle/carrier of claim 14 (i.e., cellulose) and the ophthalmologic condition to be presbyopia of claim 24.

**Marmo (‘484)** teaches methods and devices for improving vision comprising a corrective ocular device, such as a corneal appliance that is placed over an eye and has a lens body (see Abstract); (p. 1, ¶s 0003, 0009). The lens may be structured to correct visual deficiencies including myopia, hyperopia, astigmatism and presbyopia (p. 4, ¶ 0065). The lens includes a gel having at least one water soluble or water swellable polymeric material, for example at least one cellulosic component (i.e., hydroxymethyl cellulose and the like) and/or one or more other water soluble or water swellable polymeric materials (p. 10, ¶s 0108-0109); (p. 11 ¶ 0115).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat ophthalmologic conditions such as presbyopia and to incorporate the cellulosic polymeric materials as taught by Marmo within the methods of Harris. One would do so with a reasonable expectation of success because Marmo teaches methods to correct visual deficiencies, including presbyopia, which comprises providing a corrective ocular device, such as a corneal lens, whereby the lens includes suitable polymeric materials, such as cellulosic components (i.e., hydroxymethyl cellulose). The expected result would be an enhanced method for improving vision disorders and conditions.

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With regards to the duration that the correction of the ophthalmologic condition lasts, as in claims 19-21, the references are silent as to this aspect. However, it would be reasonably expected that the duration of treatment that results from correction would last for an extended period of time, in view of the fact that the prior art of record teaches the same methods and utilizes the same techniques as employed by the Applicant. The prior art clearly recognizes and teaches application of enzymes to contact lens to effectively treat ocular conditions (i.e., presbyopia) and thus employs treatment methods as claimed. Hence, the duration that the correction of the ophthalmologic condition lasts would reasonably be expected to be for an extended period of time (i.e., 1 year).

Thus, given the teachings of the combined references, the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

\* \* \* \* \*

***Pertinent Art***

Prior art cited of interest by the Examiner:

Breger (U.S. Pat. No. 4,418,991) (December 1983)

\* \* \* \* \*

***Conclusion***

Claims 1-3, 8-14, 16 and 18-24 are rejected.

Claims 4-7, 15, 17 and 25-50 are withdrawn (non-elected invention).

--No claims are allowed at this time.

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### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

*hns*

July 1, 2010



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